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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/026,106	12/21/2001	Jean-Christophe Renauld	LUD 5752 DIV JEL/NDH (101	7513

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EXAMINER	
HAMUD, FOZIA M	

ART UNIT	PAPER NUMBER
1647	23

DATE MAILED: 09/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

File copy

Office Action Summary	Application No. 10/026,106	Applicant(s) RENAULD ET AL.	
	Examiner Fozia M Hamud	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with th correspondence address --

Period f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 July 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) *13-23,26-28 and 30-37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,24,25 and 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of the invention of Group I and SEQ ID NO:7, (claims 1-12, 24, 25 and 29) in Paper No. 22, filed on 24 July 2003 is acknowledged.

The traversal is on the grounds that nucleotide sequence SEQ ID NO:7 encodes the amino acid sequence of SEQ ID NO:9, therefore, the Examiner's comments on distinction and separability are clearly wrong. Applicants also argue that the nucleotide of SEQ ID NO:8 encodes the amino acid of SEQ ID NO:10. Applicants further submit that SEQ ID NO: 9 is a splice variant of SEQ ID NO:7, therefore, these molecules are related. Applicants also submit that SEQ ID NO:8 and 10 are identical through amino acid 177, where 4 amino acids that are present in SEQ ID NO:8 are missing in SEQ ID NO:10, thus the coding regions of these polypeptides are related. Finally, Applicants argue to further aid the biotechnology industry, the commissioner allows a reasonable number of sequences to be claimed in an application and that the office considers 10 sequences to be a reasonable number. Instant claims only recite 4 sequences, and is within the commissioner's guidelines.

Applicants' grounds of traversal have been fully considered but are not found persuasive .

Firstly, SEQ ID NO:7 encodes the amino acid sequence set forth in SEQ ID NO:8 (SEQ ID NO:7 does not encode SEQ ID NO:9, as both SEQ ID NO:7 and SEQ ID NO:9 are nucleotide sequences), which consists of 522 amino acid residues. While SEQ ID NO:9 encodes the amino acid sequence set forth in SEQ ID NO:10, which consists of

244 amino acid residues. The polypeptide of SEQ ID NO:8 contains 278 more amino acid residues than that of SEQ ID NO:10, therefore, even if the two polypeptides are identical in the first 177 amino acid residues, they have more differences than they have similarities. Secondly, according to MPEP §803.04, nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C.121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Furthermore, as was set forth in the restriction requirement mailed on 14 July 2003 in Paper NO:21, nucleotide sequences and the encoded polypeptides are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function and each has an independent use, that is distinct for each invention which cannot be exchanged. The nucleic acid can be used to make a hybridization probe or can be used in gene therapy as well as in the production of the encoded polypeptide, therefore, the Examiner's assertion that nucleotide sequences and the encoded amino acid sequences are distinct is not wrong.

With respect to applicant's argument directed to sequences, in which the Commissioner authorized a partial waiver of restriction practice, allowing the examination of up to ten sequences, the issue in question was a partial waiver of restriction practice to allow examination of up to ten sequences. This waiver was issued

in 1996, however since then, the nucleic acid and protein databases that must be searched for each of the independent and distinct sequences claimed herein have multiplied many fold in size, such that it is now burdensome to search more than a single sequence in an application. Further, the waiver allowed, but did not require the Examiner to search ten sequences.

The restriction requirement is still deemed proper and is therefore made FINAL.

Claims 1-37 are pending. Claims 1-12, 24, 25 and 29 are drawn to the elected invention, thus, these claims will be searched and examined, in so far as they pertain to SEQ ID NO:7. Claims 13-23, 26-28 and 30-37are withdrawn from consideration by the Examiner as they are drawn to non-elected inventions.

Claim objections

2a. Claims 1-3 and 29 are objected to because of the following informalities:

Claims 1-3 and 29 are objected to because it is recites non-elected SEQ ID Nos.

Appropriate correction is required.

Specification:

3a. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.

(d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
(e) BACKGROUND OF THE INVENTION.
(1) Field of the Invention.
(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(f) BRIEF SUMMARY OF THE INVENTION.
(g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(h) DETAILED DESCRIPTION OF THE INVENTION.
(i) CLAIM OR CLAIMS (commencing on a separate sheet).
(j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

3b. Instant Application contains 4 figures, which appear to represent SEQ IDNOs:7, 8, 9 and 10, however, instant specification lacks the section that describes these figures. Appropriate correction is required.

3c. Instant specification states that Patent Application Serial No. 09/913,735 filed on July 26 2001, describes members of the class II cytokine receptor family, (page 3, second paragraph). However, Patent Application Serial No. 09/915,735 is the application that describes members of the class II cytokines not 09/913,735.

Claim rejections-35 USC § 101/112

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4a. Claims 1-12, 24, 25 and 29 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Claims 1-12, 24, 25 and 29 of the instant invention are directed to an isolated nucleic acid encoding a polypeptide that comprises of amino acid f SEQ ID NO:8, a vector comprising said nucleic acid, a recombinant host cell comprising said vector and a method of producing the encoded protein.

The specification describes the claimed nucleic acid as encoding a novel receptor designated as "LICR-2", and states that it has 24% homology with IL-20R, 22% amino acid homology with IL-22BP and IL-20Rβ and 21% homology with IL-22R, (see page 5, last paragraph). The specification also states that the LICR-2 ligand has been identified as AK155, (page 7).

However, although the instant specification discloses that the LICR-2 of the instant invention binds to AK155, it does not disclose any information regarding physiological role of the protein encoded by the claimed nucleic acid. Instant specification asserts that the polypeptide encoded by the claimed nucleic acid can be used to regulate AK155 activity. However, to date nothing is known about the physiological role of Ak115 (also known as IL-26), therefore, one of ordinary skill in the art would not know how to use the LICR-2 of the instant invention. One of ordinary skill in the art would not reasonably expect that the LICR-2 of the instant invention would have same physiological role of the IL-20R, just because it shares 24% identity to IL-20R.

While, the instant specification asserts that the polypeptide encoded by the claimed nucleic acid can be used therapeutically, and discloses conventional protein and nucleic acid administration techniques, it does not disclose specific diseases which can be treated or diagnosed using the claimed nucleic acid or the encoded polypeptide. The specification establishes no connection between any physiological condition or disorder and the ILCR-2 or AK155 that binds to it. Instant specification does not disclose conditions in which the LICR-2 or its ligand are over expressed or under expressed. Therefore, one of ordinary skill in the art would not be able to predict the physiological importance of the polypeptide encoded by the claimed nucleic acid. The claimed invention is directed to a nucleic acid encoding a polypeptide of as yet undetermined biological significance, which has no nexus to any disorder or disease, therefore, unless Applicants demonstrate the physiological significance or the biological role of the instant nucleic acid and the protein it encodes, the claimed invention is not supported by either a specific and substantially asserted utility or a well established utility.

4b. Claims 1-12, 24, 25 and 29 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantially asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Instant specification does not define the physiological role of the LICR-2 polypeptide encoded by the claimed nucleic acid, neither does it establish a link between this protein and a disease or a physiological condition. Therefore, there is no specific and substantial asserted utility or well established utility for the claimed nucleic acid or the encoded

protein. The specification discloses only the sequence of the claimed nucleic acid and the encoded protein, and that it binds to AK155, however, that is insufficient to establish a specific or substantial utility for the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The following is a quotation of the second paragraph of 35 U.S.C. 112:
>
> **The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

5. Claims 1-12, 24, 25 and 29 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5a. Claim 1 is rejected as vague and indefinite reciting ".....,, hybridizes under stringent conditions....", which is a conditional term and renders the claim indefinite. This rejection could be obviated by supplying specific conditions supported by the specification which Applicants consider to be " stringent".

Claims 2-12, 24 and 25 are vague and indefinite in so far as they depend on claim 1 for the limitation set forth directly above.

5b. Claim 29 recites "an oligonucleotide consisting of from 17 to 100 contiguous nucleotides of SEQ ID NO:7", however, it is unclear whether the claimed oligonucleotide consists from nucleotide number of 17 to nucleotide number or 100 of SEQ ID NO:7, or whether it should contain 17 to 100 contiguous nucleotides. If Applicants intended to claim an oligonucelotide which consists between 17 to 100 contiguous nucleotides, then it is unclear whether it should consist 17, 30, 35, 99, 100 contiguous nucleotides. Thus

the metes and the bounds of the claim can't be ascertained. Appropriate correction is required.

Conclusion

6. No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday, Wednesday-Thursday, 6:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Fozia Hamud
Patent Examiner
Art Unit 1647
25 September 2003

GARY KUNZ
SUPERVISORY PATENT EXAMINER
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